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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,273	09/16/2003	George D. Hermann	506512002000	3435

7590 02/06/2007
Novare Surgical Systems Inc.
10231 Bubb Road
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EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/664,273

Applicant(s)

HERMANN ET AL.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5-13, 15-21 and 23-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-13, 15-21 and 23-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/23/04.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 4, 14, and 22 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/22/06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 19, 20, 48 and 49 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fogarty (US 4821719).

Regarding Claim 1, Fogarty teaches an insert (60) for attachment to a jaw-type surgical instrument (10) adapted for grasping or occluding a vessel (V), said insert comprising a compliant cushion (36) having a tissue-engaging contact surface (30) and having a plurality of molded, hooked traction elements on at least a region of said surface (fig. 2).

The limitation in claim 1: "molded hooked traction elements" is being treated as a product by process limitation, in that the "molded hook elements," refers to the process of making the device and not to the final product created. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability

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of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP §2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Thus, in this case, a device wherein the hooked traction elements are molded is directed to the method of making the device and not the final product made. It appears the product disclosed by Fogarty would be the same and would perform equally well as that *claimed*; especially since both applicant's product and the prior art have the same final shape and structure and perform the same function of a device being formed with molded hooked elements.

Regarding Claim 2, Fogarty teaches the insert of claim 1 wherein said molded, hooked traction elements are configured to have at least one crook (fig. 2).

Regarding Claim 19, Fogarty teaches a surgical instrument comprising at least one jaw (26) having a compliant clamping surface (36) adapted for grasping or occluding a vessel (V), the clamping surface having a plurality of molded, hooked traction elements on at least a region of said surface (fig. 2).

Regarding Claim 20, Fogarty teaches the surgical instrument of claim 19 wherein said molded, hooked traction elements are configured to have at least one crook (fig. 2).

Regarding Claim 48, Fogarty teaches the method of occluding a vessel or other body conduit comprising the steps of: (a) providing a jaw-type surgical instrument

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comprising at least one jaw (26) having a compliant clamping surface (36) adapted for grasping or occluding a vessel (V), the clamping surface having a plurality of molded, hooked traction elements on at least a region of said surface (fig. 2); (b) contacting said clamping surface with a vessel or other body conduit; and (c) actuating said instrument to occlude said vessel or other body conduit (fig. 2).

Regarding Claim 49, Fogarty teaches a method of grasping tissue comprising the steps of: (a) providing a jaw-type surgical instrument comprising at least one jaw (26) having a compliant clamping surface (36) adapted for grasping or occluding a vessel, the clamping surface having a plurality of molded, hooked traction elements on at least a region of said surface; (b) contacting said clamping surface with tissue; and (c) actuating said instrument to grasp said tissue (fig. 2).

Claims 15-18 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty

Fogarty teaches an insert for attachment to the jaw of a surgical clamp, said insert comprising a compliant cushion (36) having a tissue-engaging contact surface and a plurality of molded, hooked traction elements located on at least a region of said surface (fig. 2), wherein when said insert is attached to said jaw, but fails to disclose the tractive force of the device as being of between about 6 and 8 pounds, or 1.5 to about 2.5 pounds is provided on a vessel clamped by the clamp. Since the device of Fogarty teaches all structural limitations as set forth by independent claims 15, 17, 30 and 32, it is inherent that the device is capable of performing the function required by the claims, that being providing traction forces of either 6-8 pounds or 1.5-2 pounds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5-7, 23-25 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty in view of Sturtz et al (US 6821284). Fogarty teaches all limitations of preceding dependent claims 1 and 19, and limitations of independent claims 42 and 45 as described with respect to claims 1 and 19, but fails to teach wherein the traction elements are not more than about .3mm in height. Sturtz teaches surgical clamp inserts, wherein the traction elements are .006 inches (.1524 mm) in order to provide lessened or reduced residual witness marks corresponding to less trauma to the clamped vessel. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fogarty with traction elements no more than .3mm in height in order to provide lessened or reduced residual witness marks corresponding to less trauma to the clamped vessel.

Claims 3, 8-13, 21, 26-29 and 34-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty in view of Romanko et al. (US 6484371). Fogarty teaches all limitations of preceding dependent claims 1 and 19, and limitations of independent claims 13, 34 and 38 as described with respect to claims 1 and 19, but fails to teach wherein the traction elements are twin crooked, or wherein the density of hooked traction elements on the surface is at least $300/\text{cm}^2$.

Regarding the limitation wherein the traction elements are twin crooked, Romanko teaches a device comprising hooked traction elements which are double crooked in order to provide twice the traction of a single crooked traction element. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fogarty with twin crooked traction elements as taught by Romanko in order to provide twice the traction of a single hooked traction element.

Regarding the limitation wherein the density of the hooked traction elements on the surface region is at least $300/\text{cm}^2$, Romanko teaches wherein the density of the hooked traction elements may be up to 465 elements per square centimeter or less. It would have been an obvious matter of design choice to provide Fogarty with a traction element density of $300/\text{cm}^2$, since applicant has not disclosed that providing such a density provides any advantage over other densities, and providing a density of $300/\text{cm}^2$ is well known in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
1/23/07


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SUPERVISORY PATENT EXAMINER
1/31/07